OCT 7 - 2004

510(K) SUMMARY

K042436

ILIZAROV PULLEY SYSTEM

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6670
CONTACT PERSON:	John Reabe
DATE SUMMARY PREPARED:	September 7, 2004
TRADE OR PROPRIETARY DEVICE NAME:	Ilizarov Pulley System
COMMON OR USUAL NAME:	External fixation system
CLASSIFICATION NAME:	Single/multiple component metallic bone fixation appliances and accessories
DEVICE CLASS:	Class II
PANEL CODE:	Orthopedic/87

DEVICE INFORMATION:

INTENDED USE:
External fixation devices are used on adults or pediatric patients as required. External fixation systems consist of various components that are used to build fixator assemblies unique to the patient's need. These devices are modular, therefore, a multitude of different fixator frame configurations are possible. External fixation devices are used for the following indications:

1. Post-Traumatic joint contracture which has resulted in loss of range of motion
2. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
3. Open and closed fracture fixation
4. Pseudoarthrosis of long bones
5. Limb lengthening by epiphyseal or metaphyseal distraction (not applicable for COMPASS Universal Hinge or JET-X™ Fixator)
6. Correction of bony or soft tissue deformities (not applicable for COMPASS Universal Hinge)
7. Correction of segmental bony or soft tissue defects
8. Joint arthrodesis
9. Infected fractures or nonunions
10. Mini external fixator systems are indicated for the management of comminuted intra-articular fractures of the distal radius.
11. Calandruccio devices are indicated for arthrodesis of the ankle or subtalar joints, as well as some select fractures, nonunion, or osteotomy of the distal tibia; and acute transverse fractures or nonunion of the distal tibia.

The indications for use listed above cover many of the external fixation systems marketed by Smith & Nephew. The indications for the Ilizarov Pulley System are pseudoarthrosis of long bones, included as number 4 above. These indications are similar to the indications of the predicate devices. The device is intended for single use.

DEVICE DESCRIPTION:
The Ilizarov Pulley System consists of cables, pulleys and a ratchet. There are two styles of cable, with or without an eyelet on one end. The cables without an eyelet are routed through the bone segment and percutaneously through the soft tissue. The cables with an eyelet are secured to the bone segment with a 3.5mm or 5.0mm diameter bone screw through the eyelet. The cable is then routed percutaneously through the soft tissue. Cables are available in diameters of 1.0mm, 1.5mm and 1.8mm and a length of 1200mm. The 1.0mm cables feature an eyelet on one end and the 1.5mm and 1.8mm cables are straight (without an eyelet).
The cable is routed through pulleys and connected to either a telescopic rod (predicate device) or a ratchet (new device). The telescopic rod or ratchet is attached to the external fixation half ring

construct. The telescopic rod or ratchet is turned to tighten the cable and move the bone segment.

The Ilizarov Pulley System is used in conjunction with the Ilizarov External Fixation System that consists of half rings, threaded rods, bolts, nuts, washers, pin clamps, wire fixation bolts, half pins and wires. The Ilizarov Pulley System will be attached to the Ilizarov External Fixation System for the indication for use of pseudoarthrosis of long bones.

The advantages of using the Ilizarov Pulley System include the ability to use fewer half pins and wires. Fewer half pins and wires will create less soft tissue displacement and less limitation to joint movement (joint stiffness).

SUBSTANTIAL EQUIVALENCE INFORMATION:

The Ilizarov Pulley System is similar to the Smith & Nephew (formerly Richards) External Fixation System (Ilizarov) (K870961) and Smith & Nephew External Fixation System (K994143) in that all the devices are used for the same indications and consist of half pins, wires, rings and various components to construct an external fixation frame. The predicate devices use half pins, wires, telescopic rods, threaded rods and slotted threaded rods to adjust the external fixation frame and transport the bone segment. The Ilizarov Pulley System uses half pins, wires, cables, pulleys and a ratchet to adjust the external fixation frame and transport the bone segment.

The Ilizarov Pulley System includes a stainless steel cable. The stainless steel cable is similar to the Smith & Nephew Orthopaedic Cable System (K87516) in that both cables are made of stainless steel and the diameters are similar (1.5mm). The Ilizarov Pulley System cable is longer (1200mm) than the predicate cable (610mm). The indications for use are not the same, but the predicate cable includes indications for general orthopaedic repair procedures and any area in which monofilament wiring is used.

The Ilizarov Pulley System is substantially equivalent to the predicate devices. The differences between the Ilizarov Pulley System and predicate devices do not affect safety and effectiveness.

SUMMARY OF TECHNOLOGICAL COMPARISON:

The Ilizarov Pulley System is substantially equivalent to the predicate devices listed in the previous section in terms of material, indications for use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Mr. John Reabe
Director of Regulatory Affairs
Smith & Nephew Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K042436
Trade/Device Name: Illizarov Pulley System
Regulation Number: 21CFR 888. 3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: September 7, 2004
Received: September 8, 2004

Dear: Mr. Reabe

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

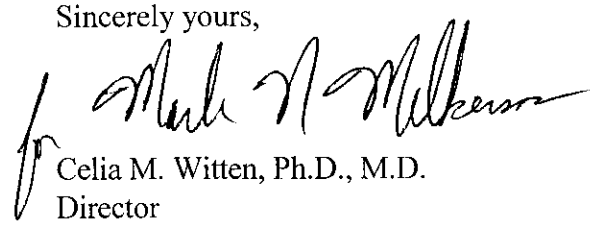
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section10(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K042436

Device Name: Ilizarov Pulley System

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042436

Indications for Use:

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Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)